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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
06/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

iplaw@stites.com

Detailed Action

This action is in response to Applicant's submission June 8, 2011 After Final.

Applicant's amendment submitted June 8, 2011 after final, has been entered as it does not raise any new issues for search and consideration. However, Applicant's arguments and request for reconsideration, submitted with the amendment, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the specification, for example paragraph 0161, shows that laminaripentaose has an unexpectedly higher biological activity than laminaritetraose, thereby overcoming the rejections under 35 USC 103(a) of record in the previous office action. However, the data provided in the specification are too unpredictable to prove any clear case of unexpected results. Specifically, the results shown in tables 5 and 6 indicate that there is no clear relation between dose, time, and TNF-alpha inducing effect for these compounds. For example, the TNF-alpha inducing effect of laminartetraose appears to have a negative dose-response curve. Additionally, laminaripentaose has a peak effect at 90 minutes for a dose of 50 µm/mouse, but a peak at 30 minutes for a dose of 250 µm/mouse. The effect of laminaripentaose at 250 µm/mouse starts at about 42.1 pg/mL, decreases to 24.4 at 90 minutes, and then increases to 79.6 at 24 hours. Given the unusual variations in these data, one of ordinary skilled in the art would suspect that the data are simply noisy and that any pattern seen it merely the result of random variation between experiments, or between experimental subjects. In view of the absence of any indication of how many mice were tested or any standard deviation

included with the data, one of ordinary skill in the art cannot tell which of these effects are real and which are due to variation between individuals, which could be quite significant if, for example, each data point represents a single mouse. As no control was used it is impossible to tell which of the data points even represent a real increase in TNF-alpha expression over baseline. It is particularly noted that for some data points, for example 30 and 60 minutes at 50 µm/mouse of 60 minutes at 250 µm/mouse, laminaritetraose actually provides a greater effect than laminaripentaose. Finally, the claims as written are generic to all dosage levels of laminaripentaose, which is counter to Applicant's assertion that the data show that laminarpentaose is unexpectedly more effective than laminartetraose. Given the odd dose-response effects shown by these data, one of ordinary skill in the art would not be able to generalize the data to all dosage levels. In particular, given the apparent inverse dose-response curve of laminaritetraose, it would be expected that even lower doses of this compound (e.g. 10µm/mouse) would be more effective than laminaripentaose. For these reasons, no unexpected results are seen over the full range of the claimed invention, and the rejections of record in the previous office action are deemed proper and maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

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/ERIC S OLSON/
Primary Examiner, Art Unit 1623
6/17/2011